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| APPLICATION NO.          | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|-------------|----------------------|---------------------|------------------|
| 10/590,255               | 08/22/2006  | Giovanni Mogna       | HOFF-41078          | 6071             |
| 86378                    | 7590        | 11/27/2009           | EXAMINER            |                  |
| Pearne & Gordon LLP      |             |                      | MARX, IRENE         |                  |
| 1801 East 9th Street     |             |                      |                     |                  |
| Suite 1200               |             |                      | ART UNIT            | PAPER NUMBER     |
| Cleveland, OH 44114-3108 |             |                      | 1651                |                  |
|                          |             |                      |                     |                  |
|                          |             |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|                          |             |                      | 11/27/2009          | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patdocket@pearne.com  
dchervenak@pearne.com

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/590,255             | MOGNA ET AL.        |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Irene Marx             | 1651                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 26 August 2009.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-10, 17-23, 28 and 29 is/are pending in the application.

4a) Of the above claim(s) 6 and 17-23 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-5, 7-10, 28 and 29 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/26/09.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

The amendment filed 8/26/09 is acknowledged.

Claims 1-5, 7-10 and 28-29 are being considered on the merits. Claims 6, and 17-23 are withdrawn from consideration as directed to a non-elected invention.

The amendment filed 8/26/09 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The definition of quintal as 100 kg. at page 10.

The basis for this definition is not provided in this record.

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7-10 and 28-29 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 are confusing in that the intended meaning of "forced hetero-fermentative" is uncertain in this context. The term "forced" in this context does not appear to encompass art recognized terminology.

Claim 4 is confusing in the recitation of further comprising "the step of providing animal feed from said fodder, wherein said method is effective to reduce the amount of aflatoxin B1 in said feed." It is unclear what is intended in this context. The target of "providing" is uncertain.

Claims 8-9 are vague, indefinite and confusing in the recitation of "quintal". This term can mean

- a) 112 pounds (50.85 kg) or
- b) 100 pounds (45.36 kg) or
- c) about 220 pounds (100 kilograms [Arabic *qintār*])

(<http://www.thefreedictionary.com/>)

Therefore, the "dose" intended cannot be determined since it is unclear which of the different meanings of "quintal" is intended. In addition, it is unclear whether the bacteria are intended to be alive or dead. Moreover, it is unclear whether dry or wet weight is intended.

Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

***Response to Arguments***

Applicant's amendment to the specification are noted, but they did not obviate the rejections made.

Therefore, the rejections are repeated as appropriate.

Claim 3 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ specific strains of *Lactobacillus* and *Leuconostoc*. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It appears that a deposit was made in this application as filed as noted on page 8, last paragraph of the specification. However, it is not clear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

**SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL**

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

***Response to Arguments***

Applicant's amendment to the specification are noted. However, there is nothing on this record to demonstrate that the strains of claim 3 are available to the public as required.

To complete the record, the deposit receipts for the strains claimed should be provided.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7-10 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable Mogna *et al.* (MI2001A002202) taken with Holzer *et al.* (Trends in Biotechnology Vol.21 No.6 June 2003)

The claims are directed to a method of eliminating or reducing the number of molds responsible for the production of mycotoxins in the feed by adding any strain of *L. plantarum* or *L. pentosus* in combination of any hetero-fermentative *Lactobacillus*, such as *Lactobacillus fermentum*, *Lactobacillus brevis* or *Leuconostoc mesenteroides*, which it is noted is not a member of *Lactobacillus*. Specifically, the strains may be *L. plantarum* LMG P-21020, LMG P-21021, LMG P-21022 or LMG P-21023 or *L. pentosus* LMG P-21019.

Mogna *et al.* disclose the addition of *L. plantarum* LMG P-21020, LMG P-21021, LMG P-21022 or LMG P-21023 or *L. pentosus* LMG P-21019 to a vegetable mass intended for ensiling to inhibit the development of harmful microorganisms in the fodder. This method has the inherent effect of eliminating and/or reducing the number of molds responsible for the production of mycotoxins in the feed, including, of course, Aflatoxin B1. See, e.g., translation, page 16, paragraph 3, page 18, paragraph 3; page 19, lines 1-8 and claim 6 and 20. That mixtures of the strains are envisioned is evidenced by at least claim 20.

The size of inocula is disclosed at page 18, paragraph 3, for example. See also rejection under 35 U.S.C. § 112, second paragraph regarding the lack of clarity for the size of "quintal" and whether dry or wet weight is intended.

The reference differs from the claimed invention in that the combination of *L. plantarum* or *L. pentosus* and heterofermentative lactic acid bacteria such as *Lactobacillus fermentum*, *Lactobacillus brevis* or *Leuconostoc mesenteroides* is not specifically disclosed. However, Holzer *et al.* disclose the combination of *L. plantarum* with the heterofermentative *L. buchneri* in fodder or silage for decreasing mold. See, e.g., page 285, col. 2, paragraph 2. Table 1 shows which bacteria are heterofermentative. Thus, one of ordinary skill in the art would have been motivated to add at least *L. plantarum* in combination with *L. buchneri* or other heterofermentative bacteria such as *Lactobacillus fermentum*, *Lactobacillus brevis* and *Leuconostoc mesenteroides* to fodder or silage with a reasonable expectation of success obtaining fodder that is infected with fewer molds or is mold-free, is more stable and less susceptible to deterioration.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Mogna *et al.* by combining *L. plantarum* or *L. pentosus* with heterofermentative bacteria such as *Lactobacillus fermentum*, *Lactobacillus brevis* and *Leuconostoc mesenteroides* in a process of producing fodder or silage as suggested by the teachings of Holzer *et al.* for the expected benefit of producing fodder with reduced or no molds that produce mycotoxins and thus obtaining fodder that is healthier, more nutritious, more stable and less susceptible to deterioration.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Applicants' arguments are moot in view of the new grounds of rejection.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/  
Primary Examiner  
Art Unit 1651